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L5: Entry 1 of 1 File: PGPB Apr 11, 2002

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TITLE: Test methods and devices

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US-CL-CURRENT: 436/518; 702/19

CLAIMS:

1. A method for differentiating between two states of an analyte that exists in a plurality of forms, which states differ from one another in the nature and/or amount of one or more forms present therein, wherein: a) at least two contemporaneous assays are conducted, the first of which has a specificity for the analyte that is essentially constant irrespective of whether the analyte is in one form or the other, and the second of which has a specificity for the analyte that differs depending on which form the analyte is in; and b) the results of the first and second assays are compared.

2. A method of testing for the existence of a menopausal condition in a human female by means of a gonadotrophin assay, wherein: a) at least two contemporaneous assays are conducted, the first of which has a specificity for the gonadotrophin that is essentially constant irrespective of whether the human female is pre-menopausal or post-menopausal, and the second of which has a specificity for the gonadotrophin that differs depending on whether the human female is pre-menopausal or post-menopausal; and b) the results of the first and second assays are compared.

3. A method according to claim 1, wherein the analyte is a gonadotrophin.

4. A method according to claim 2 or 3, wherein the gonadotrophin is follicle stimulating hormone (FSH).

5. A method according to any one of the preceding claims, wherein both contemporaneous assays are sandwich-format assays.

6. A method, according to any one of claims 2-5, wherein each of said at least two contemporaneous assays uses an antibody pair directed against the alpha and beta

peptide chains of the gonadotrophin, but both members of the antibody pair in the first assay differ from the members of the antibody pair in the second assay.

7. A method according to any one of the preceding claims, wherein each assay provides a quantitative result, and the ratio of the two results is taken as indicative of menopausal status.

8. A method according to any one of the preceding claims, wherein the at least two contemporaneous assays are repeated at intervals of at least one week to determine whether the menopausal status is changing.

9. A method according to claim 8, wherein the human subject is one undergoing a course of HRT.

10. An assay device for testing a body fluid sample obtained from a human female, the device having a first analyte-responsive (preferably gonadotrophin-responsive) signal-producing means that provides a readable signal that, relative to a reference reference standard, is constant irrespective of whether the sample is derived from a a pre-menopausal or post-menopausal subject, and a second analyte-responsive (preferably gonadotrophin-responsive) signal-producing means that provides a readable signal that, relative to a reference standard, differs depending on whether whether the sample is derived from a pre-menopausal or post-menopausal subject.

11. An assay device according to claim 10, wherein the gonadotrophin is FSH.

12. An assay device according to claim 10 or claim 11, wherein each readable signal is caused by the binding in a detection zone of a specific binding agent labelled with a particulate direct label.

13. A method according to claim 1, or an assay device according to claim 10, substantially as hereinbefore described.

14. A method according to claim 4, or an assay device according to claim 11, wherein wherein the first assay, or first gonadotrophin-responsive signal-producing means, as appropriate, uses a pair of anti-FSH antibodies that detect "total" FSH.

15. An anti-FSH monoclonal antibody as expressed by hybridoma cell line ECACC 00032004.

16. An anti-FSH monoclonal antibody as expressed by hybridoma cell line ECACC 00032005.

17. A method according to claim 4, or an assay device according to claim 11, wherein wherein the second assay uses either or both of the anti-FSH antibodies claimed in claims 15 and/or 16.

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L17: Entry 3 of 51 File: PGPB Mar 25, 2004

DOCUMENT-IDENTIFIER: US 20040058383 A1
TITLE: Methods and reagents for determining the amount of hLH-beta core fragment in a sample

CLAIMS:

1. A method for predicting the likely timing of the onset of menopause for a perimenopausal female subject by determining the amount of hLH.beta.cf in a sample from the subject comprising the steps of: a. contacting a sample from the subject with an antibody which specifically binds to hLH.beta.cf without substantially cross-reacting with hLH, hLH.beta. or hCG.beta.cf, under conditions permitting formation of a complex between the antibody and hLH.beta.cf; b. measuring the amount of complex formed, so as to thereby determine the amount of hLH.beta.cf in the sample; and c. comparing the amount of hLH.beta.cf in the subject's sample determined in step (b) with either (i) the amount determined for known postmenopausal female subject or (ii) the amount determined for a sample from a known premenopausal female subject, wherein an amount of hLH.beta.cf in the sample similar to the amount of hLH.beta.cf in the known postmenopausal sample indicates temporal proximity to the onset of menopause, and an amount of hLH.beta.cf in the sample similar to the amount of hLH.beta.cf in the known premenopausal sample indicates temporal distance from the onset of menopause for the subject.

8. A method for predicting the likely timing of the onset of menopause for a perimenopausal female subject comprising the steps of: a. contacting a urine sample from the subject with a capturing antibody which specifically binds to hLH.beta.cf without substantially cross-reacting with hLH, hLH.beta. or hCG.beta.cf under conditions permitting binding of the antibody with any hLH.beta.cf present in the sample wherein the capturing antibody is bound to a matrix b. separating hLH.beta.cf bound to the matrix bound capturing antibody from hLH.beta.cf not so bound; c. contacting the hLH.beta.cf bound matrix to the capturing antibody with a second antibody which specifically binds to hLH.beta.cf that is bound to the capturing antibody without cross reacting with hLH, hLH.beta. or hCG.beta.cf under conditions permitting binding of the second antibody to hLH.beta.cf bound to the capturing antibody; d. measuring the amount of the second antibody bound to the hLH.beta.cf that is bound to the matrix bound capturing antibody so as to thereby determine the amount of hLH.beta.cf in the sample; and e. comparing the amount of hLH.beta.cf in the subject's sample determined in step (d) with either (i) the amount determined for a sample from a known postmenopausal female subject or (ii) the amount determined for a sample from a known premenopausal female subject, wherein an amount of hLH.beta.cf in the sample similar to amount of hLH.beta.cf in the known postmenopausal sample indicates temporal proximity to the onset of menopause, and the amount of hLH.beta.cf in the sample similar to the amount of hLH.beta.cf in the known premenopausal sample indicates temporal distance from the onset of menopause for the subject.

16. A method for determining the likely timing of the onset of menopause for a perimenopausal female subject comprising: a. obtaining a series of samples from the female subject over a period of time; and b. determining the amount of hLH.beta.cf

in each of the samples, the presence of elevated levels of basal hLH.beta.cf in each each of the samples indicating that the onset of menopause in the subject is likely to occur in the near future.

17. The method of claim 16, wherein step (b) comprises: a. contacting a sample from the subject with an antibody which specifically binds to hLH.beta.cf without substantially cross-reacting with hLH, hLH.beta., or hCG.beta.cf, under conditions permitting formation of complex between the antibody and hLH.beta.cf; and b. measuring the amount of complex formed, so as to thereby determine the amount of hLH.beta.cf in the samples; and c. comparing the amount of hLH.beta.cf in the subject's sample determined in step (b) with either (i) the amount determined for known postmenopausal female subject or (ii) the amount determined for a sample from a known premenopausal female subject, the stable presence of elevated levels of basal hLH.beta.cf indicating temporal distance from the onset of menopause in the subject.

33. A method for determining the efficacy of hormone replacement therapy in a perimenopausal female subject comprising the steps of: a. contacting a sample from the subject with an antibody which specifically binds to hLH.beta.cf without substantially cross-reacting with hLH, hLH.beta. or hCG.beta.cf, under conditions permitting formation of a complex between the antibody and hLH.beta.cf; b. measuring the amount of complex formed, so as to thereby determine the amount of hLH.beta.cf; and c. comparing the amount of hLH.beta.cf measured in step (b) with either (i) the amount determined for a sample from a subject taken prior to the commencement of therapy or (ii) the amount determined for a sample after a prior course of therapy (iii) the amount determines for a sample from a known premenopausal female subject or (iv) the amount determine for a sample from a known postmenopausal female, wherein differences in the amounts of hLH.beta.cf in the sample indicate efficacy of the hormone replacement therapy for the subject; amounts of hLH.beta.cf in the sample similar to amounts or hLH.beta.cf samples from known premenopausal subjects indicates efficacy of the hormone replacement therapy for the subject; amounts of hLH.beta.cf molecule in the sample similar to amounts of hLH.beta.cf in the sample from known postmenopausal subjects indicates lack of efficacy of the hormone replacement therapy for the subject.

41. A diagnostic kit for predicting the likely timing of the onset of menopause for a perimenopausal female subject by determining the amount of hLH.beta.cf in a sample sample from the subject comprising: a. a solid matrix to which an antibody which specifically binds to hLH.beta.cf without substantially cross-reacting with hLH, hLH.beta. or hCG.beta.cf, under conditions permitting formation of a complex between the antibody and hLH.beta.cf is bound; and b. a second antibody labeled with a detectable marker; and c. reagents permitting the formation of a complex between the antibody and hLH.beta.cf.

42. The diagnostic kit of claim 41, further comprising control sample(s) selected from the group consisting of premenopausal sample(s), perimenopausal sample(s), postmenopausal sample(s) and male sample(s).

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L16: Entry 27 of 200 File: PGPB Feb 5, 2004

DOCUMENT-IDENTIFIER: US 20040023878 A1
TITLE: Gnrh analogues for treatment of urinary incontinence

CLAIMS:

1. Use of at least one GnRH analogue for the preparation of a medicament for the treatment and/or prevention of side effects of ovarectomy or symptoms associated with reproductive senescence in female mammals.

2. Use according to claim 1 wherein said GnRH analogue is selected from the group consisting of peptides, polypeptides or proteins.

6. Use according to anyone of the preceding claims characterized in that said GnRH analogue is selected from the group consisting of deslorelin acetate, goserelin acetate, nafarelin acetate, buserelin acetate, triptorelin acetate, gonadorelin acetate, leuprolid acetate, danazolum, Cetrorelix or mixtures thereof.

10. Use according to anyone of the preceding claims wherein said medicament comprises different unit forms, at least one for the at least one GnRH analogue and at least one for an at least one further active substance.

11. Use according to anyone of the preceding claims wherein said medicament is a slow release formulation for at least the GnRH analogue.

12. Use according to anyone of claims 1 to 6 wherein said medicament comprises as active compounds only at least one GnRH analogue.

13. Use according to anyone of the preceding claims, characterized in that the female mammal is a human female pre-or postmenopausal, or a female dog.

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L16: Entry 68 of 200 File: PGPB Mar 13, 2003

DOCUMENT-IDENTIFIER: US 20030050289 A1
TITLE: Combination of drospirenone and an estrogen sulphamate for HRT

CLAIMS:

3. The dosage unit according to claim 2, wherein the deficient endogenous levels of estrogen are caused by natural menopause, pre-menopause, peri-menopause, post-menopause, hypogonadism, castration, hysterectomy, or primary ovarian failure.

7. The dosage unit according to claim 5, wherein the dose of estrogen sulphamate is sufficient for the treatment of breast cancer in a woman, such as estrogen-dependent breast cancer.

29. The method according to claim 28, wherein the deficient endogenous levels of estrogen are caused by natural menopause, pre-menopause, peri-menopause, post-menopause, hypogonadism, castration, hysterectomy, or primary ovarian failure.

33. The method according to claim 28, wherein the dose of estrogen sulphamate is sufficient for the treatment of breast cancer in a woman, such as estrogen-dependent breast cancer.

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L17: Entry 7 of 18 File: USPT May 20, 1997

DOCUMENT-IDENTIFIER: US 5631170 A
TITLE: Method for improving measurement precision in evanescent wave optical biosensor assays

CLAIMS:

1. A method of improving measurement precision in an optical biosensor assay for a ligand in a sample which comprises the steps of

i) incubating the sample in contact with a measurement surface which carries a directly or indirectly immobilised measurement reagent appropriate to the assay and which additionally carries an amount of a directly or indirectly immobilised reference reagent which gives rise to a reference signal, independent of the amount of ligand present in the sample, at the measurement surface, and prior to, during, or subsequent to the said incubation of the sample measuring said reference signal by a method appropriate to the assay;

ii) simultaneously with or sequentially to the said incubation of the sample in i) introducing one or more labelled ancillary reagents appropriate to the assay whereby if ligand is present in the sample, a complex involving said measurement reagent and at least one of said ligand or said labelled ancillary reagent(s) is formed giving rise to a detectable assay signal which is a first function of the amount of ligand (if any) present in the sample; and

iii) subsequently monitoring the assay signal arising from the measurement surface by a method appropriate to the assay and, comparing the reference signal with the assay signal, thereby determining using an appropriate algorithm whether and/or the extent to which the ligand under assay is present in the sample.

2. A method as claimed in claim 1 additionally comprising the steps of

iv) simultaneously or sequentially to the incubation in step i), incubating the sample, if desired together with one or more labelled ancillary reagents, with one or more further calibration surface(s) separated from the measurement surface onto each of which is immobilised a calibration reagent appropriate to the assay, the calibration reagent either being such to give rise to a zero or non-zero signal or being such as to form a complex involving at least one of said ligand or said labelled ancillary reagent(s) whereby any such complex gives rise to a non-zero signal (or, where no such complex is formed, which would be formed if ligand were present), the signal being either a second function of or independent of the amount of ligand (if any) present in the sample;

v) monitoring the calibration signal(s) arising from the calibration surface(s); and

vi) subsequently comparing the calibration signal(s) to both the assay signal and reference signal and, using an appropriate algorithm, the measure of the extent to which the ligand under assay is present in the sample, as derived from the assay signal and reference signal is thereby calibrated.

4. A method as claimed in claim 2, the assay being a sandwich assay, wherein

in step i) and ii) a labelled specific binding partner for the ligand under assay is present as a labelled ancillary reagent and the measurement reagent (or optionally a reagent precomplexed with or capable of forming a complex involving the measurement reagent) is a further specific binding partner for the ligand under assay, said further specific binding partner being directed to an epitope of the ligand under assay different to the epitope to which the labelled specific binding partner is directed;

and wherein in step iv), either a) the calibration reagent (or optionally a reagent precomplexed with or capable of forming a complex involving the calibration reagent) is a specific binding partner for the ligand under assay, a labelled specific binding partner for the ligand under assay is present as a labelled ancillary reagent and a known amount of the ligand under assay precomplexed to its labelled specific binding partner is present as a yet further ancillary reagent or b) a labelled specific binding partner for the ligand under assay is present as a labelled ancillary reagent and the calibration reagent (or optionally a reagent precomplexed with or capable of forming a complex involving the calibration reagent) is a known amount of the ligand under assay precomplexed to its immobilized specific binding partner or c) a ligand distinct from the ligand under assay is present as an ancillary reagent and the calibration reagent (or optionally a reagent precomplexed with or capable of forming a complex involving the calibration reagent) is a labelled specific binding partner for the ligand distinct from the ligand under assay or d) the calibration reagent is a labelled binding partner non-specific for any labelled ancillary reagent(s) present or e) the calibration reagent gives rise to the desired zero or non-zero signal without the need for the presence of a labelled ancillary reagent.

9. A method as claimed in claim 1, the assay being a sandwich assay, wherein in step i) and ii) a labelled specific binding partner for the ligand under assay is present as a labelled ancillary reagent and the measurement reagent (or optionally a reagent precomplexed with or capable of forming a complex involving the measurement reagent) is a further specific binding partner for the ligand under assay, said further specific binding partner being directed to an epitope of the ligand under assay different to the epitope to which the labelled specific binding partner is directed.

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L17: Entry 3 of 18 File: USPT Jan 5, 1999

DOCUMENT-IDENTIFIER: US 5856203 A
TITLE: Sensor device for sandwich assay

CLAIMS:

1. A sensor device for use in a sandwich assay for a ligand in a sample which comprises i) a first discrete measurement zone having a region on which is immobilised directly or indirectly a first specific binding partner for the ligand under assay or a reagent precomplexed with or capable of forming a complex with a specific binding partner for the ligand under assay, which measurement zone additionally contains, in releasable form, a first known amount of labelled second specific binding partner for the ligand under assay, the second specific binding partner being directed to an epitope of the ligand under assay different to the epitope to which the first specific binding partner is directed; and ii) a second discrete reference zone having a region on which is immobilised directly or indirectly a first specific binding partner for the ligand under assay or a reagent precomplexed with or capable of forming a complex with a specific binding partner for the ligand under assay, which reference zone additionally contains, in releasable form, a known amount of ligand analogue and separately contains, in releasable form, a second known amount of a labelled second specific binding partner for the ligand under assay, said second known amount being less than the aforementioned first known amount in the measurement zone.

4. A device for use in a sandwich assay for a ligand in a sample in which one or more additional calibration step(s) are carried out being a device as claimed in claim 1 additionally comprising one or more further discrete calibration zone(s) having a region on which is immobilised directly or indirectly a calibration reagent appropriate to the assay.

5. A device as claimed in claim 1 being a specifically-reactive sample-collecting and testing device for use in a sandwich assay for a ligand, possessing a cavity having two regions I and II mutually separated and each region carrying a layer comprising, in releasable form, a reagent suitable for the desired assay, said regions on which said layers are carried having a surface of a first solid plate fashioned of transparent material, wherein the wall of the or each cavity opposite to said first plate comprises a second plate fashioned of transparent material and able to act as a light transmissive waveguide, the second plate having on its surface adjacent the cavity two regions IV and V corresponding in orientation to the aforementioned regions I and II respectively, each of regions IV and V carrying a layer comprising an immobilised reagent suitable for the desired assay, said regions being arranged such that region I is paired with region IV and region II is paired with region V such that one of said pairs provides the measurement zone and the other pair provides the reference zone.

8. A method of sandwich assay for a ligand in a sample which comprises the steps of

i) incubating the sample with a device as claimed in claim 1,

ii) monitoring a signal appropriate to the assay arising from the measurement zone of said device,

iii) simultaneously or sequentially to the said monitoring in ii), monitoring a signal appropriate to the assay arising from the reference zone(s) of said device; and

iv) comparing the signal(s) from the reference zone with the signal from the assay zone, thereby determining using an appropriate algorithm whether and/or the extent to which the ligand under assay is present in the sample.

9. A method of sandwich assay for a ligand in a sample in which one or more additional calibration step(s) are carried out, being a method as claimed in claim 8 wherein in step i) the sample is incubated in the presence of the device additionally carrying on a first plate one or more further zone(s) carrying a layer comprising, in soluble releasable form, ancillary reagent(s) suitable for the desired assay and additionally carrying on a second plate one or more calibration zone(s) each of which is corresponding in orientation to one of said further zone (s) on said first plate, and each of which is carrying a layer comprising an immobilised calibration reagent, said method additionally comprising the steps of

v) simultaneously or sequentially to the incubation in step i), incubating the sample, if desired together with one or more ancillary reagents, with the calibration zone(s) of the device;

vi) monitoring signal(s) appropriate to the assay arising from the calibration zone (s); and

vii) subsequently comparing the signal(s) from the calibration zone to both the signal from the assay zone and the signal from the reference zone and, using an appropriate algorithm, the measure of the extent to which the ligand under assay is present in the sample, as derived from the signals is thereby calibrated.

15. A device for use in a sandwich assay for a ligand in a sample in which one or more additional calibration step(s) are carried out being a device as claimed in claim 2 additionally comprising one or more discrete calibration zone(s) having a region on which is immobilised directly or indirectly a calibration reagent appropriate to the assay.

16. A device as claimed in claim 2 being a specifically-reactive sample-collecting and testing device for use in a sandwich assay for a ligand, possessing a cavity having two regions I and II mutually separated and each region carrying a layer comprising, in releasable form, a reagent suitable for the desired assay, said regions on which said layers are carried having a surface of a first solid plate fashioned of transparent material, wherein the wall of the or each cavity opposite to said first plate comprises a second plate fashioned of transparent material and able to act as a light transmissive waveguide, the second plate having on its surface adjacent the cavity two regions IV and V corresponding in orientation to the aforementioned regions I and II respectively, each of regions IV and V carrying a layer comprising an immobilised reagent suitable for the desired assay, said regions being arranged such that region I is paired with region IV and region II is paired with region V such that one of said pairs provides the measurement zone and the other pair provides the reference zone.

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L17: Entry 4 of 18 File: USPT Mar 10, 1998

DOCUMENT-IDENTIFIER: US 5726064 A
TITLE: Method of assay having calibration within the assay

CLAIMS:

2. A competitive specific binding method for determining a ligand in a liquid sample, comprising:

(A) contacting the liquid sample to a capillary-fill device, said device comprising a measurement zone and at least one spatially distinct calibration zone wherein

(1) the measurement zone comprises (a) a known amount of a releasable first ancillary specific binding reagent and (b) a measurement surface comprising an immobilized measurement specific binding reagent capable of specifically binding with at least one of the ligand and the first ancillary specific binding reagent, wherein the first ancillary specific binding reagent is provided either on a surface surface of the measurement zone separate from the measurement surface or prebound to to the immobilized measurement specific binding reagent, and is either (i) labelled ligand analogue or (ii) labelled specific binding partner for the ligand or (iii) a combination of the labelled ligand analogue and specific binding partner for the ligand,

(2) the calibration zone comprises

(c) a known amount of a releasable second ancillary specific binding reagent and a calibration surface comprising an immobilized calibration specific binding reagent having binding sites identical in structure to those of the immobilized measurement specific binding reagent and capable of specifically binding with at least one of the ligand and the second ancillary specific binding reagent or

(d) a calibration surface comprising a known amount of immobilized label, wherein the second ancillary specific binding reagent is provided either on a surface of the the calibration zone separate from the calibration surface or prebound to the immobilized calibration specific binding reagent, and is (i) said labelled ligand analogue or (ii) said labelled specific binding partner for the ligand or (iii) said said combination of the labelled ligand analogue and specific binding partner for the ligand, and

(3) the releasable reagents remain in their respective zones without mixing with each other in the method following either sequential or simultaneous contact with the liquid sample (a) to form a labelled measurement complex immobilized on the measurement surface in an amount dependent on the amount of the ligand present in the liquid sample and (b) to provide a calibration signal by (c) forming either a labelled calibration complex immobilized on the calibration surface in an amount either dependent on or independent of the amount of the ligand present in the liquid sample or (d) due to said known amount of immobilized label on the calibration surface; and

(B) measuring and comparing the amount of label on the measurement and calibration

surfaces to determine the presence or amount of the ligand in the liquid sample.

6. A direct specific binding method for determining a ligand in a liquid sample, comprising:

(a) contacting the liquid sample to a capillary-fill device, said device comprising (1) a measurement zone, (2) at least one spatially distinct calibration zone and (3) (3) at least one spatially distinct auxiliary calibration zone wherein

(1) the measurement zone comprises (a) a known amount of a releasable first ancillary specific binding reagent and (b) a measurement surface comprising an immobilized measurement specific binding reagent capable of specifically binding with at least one of the ligand and the first ancillary specific binding reagent, wherein the first ancillary specific binding reagent is provided either on a surface surface of the measurement zone separate from the measurement surface or prebound to to the immobilized measurement specific binding partner reagent, and is a specific binding partner for the ligand,

(2) the calibration zone comprises

(c) a known amount of at least one releasable second ancillary specific binding reagent and a calibration surface comprising an immobilized calibration specific binding reagent having binding sites identical in structure to the those of the immobilized measurement specific binding reagent and capable of specifically binding binding with at least one of the ligand and the second ancillary specific binding reagent, or

(d) a calibration surface comprising a known amount of an immobilized calibration complex comprising the immobilized calibration specific binding reagent and either the ligand or the second ancillary specific binding reagent, wherein the second ancillary specific binding reagent is provided either on a surface of the calibration zone separate from the calibration surface or prebound to the immobilized calibration specific binding reagent, and is (i) said ligand analogue or or (ii) said specific binding partner for the ligand, and

(3) the auxiliary calibration zone comprises

(e) either a known amount of at least one releasable third ancillary specific binding reagent and a first auxiliary calibration surface comprising an immobilized first auxiliary calibration specific binding reagent having binding sites identical in structure to those of the immobilized measurement specific binding reagent and capable of specifically binding to a least one of the ligand and the third ancillary ancillary specific binding reagent, or

(f) a first auxiliary calibration surface comprising an immobilized first auxiliary nonspecific binding reagent, wherein the third ancillary specific binding reagent is is provided either on a surface of the first auxiliary calibration zone separate from the first auxiliary calibration surface or prebound to the immobilized first auxiliary calibration specific binding reagent, and is (i) said ligand analogue or (ii) said specific binding partner for the ligand or (iii) a nonspecific binding ligand which binds to the immobilized first auxiliary nonspecific binding reagent,

(4) the releasable reagents remain in their respective zones without mixing with each other in the method following either sequential or simultaneous contact with the liquid sample (a) to form an unlabelled measurement complex immobilized on the measurement surface in an amount dependent on the amount of the ligand present in the liquid sample, (b) to provide an unlabelled calibration signal by (c) forming either an unlabelled calibration complex immobilized on the calibration surface in an amount either dependent on or independent of the amount of the ligand present in the liquid sample or (d) due to said known amount of an immobilized calibration

complex comprising the immobilized calibration specific binding reagent and either the ligand or the second ancillary specific binding reagent, and to provide an unlabelled auxiliary calibration signal by (d) forming either an unlabelled first auxiliary calibration complex immobilized on the first auxiliary calibration surface surface in an amount either dependent on or independent of the amount of the ligand present in the liquid sample or (f) forming an unlabelled nonspecific binding complex in an amount dependent upon nonspecific binding background, and

(B) measuring and comparing a change in property of the measurement, calibration and and auxiliary calibration surfaces due to any change in mass on the measurement, calibration and auxiliary calibration surfaces due to the formation of said unlabelled measurement, calibration and first auxiliary calibration complexes to determine the presence or amount of the ligand in the liquid sample.

7. A sandwich specific binding method for determining a ligand in a liquid sample, comprising:

(A) contacting the liquid sample to a capillary-fill device, said device comprising a measurement zone and at least one spatially distinct calibration zone wherein:

(1) the measurement zone comprises (a) a known amount of a releasable first ancillary specific binding reagent and (b) a measurement surface comprising an immobilized measurement specific binding reagent capable of specifically binding to at least one of the ligand and the first ancillary specific binding reagent, wherein the first ancillary specific binding reagent is provided either on a surface of the measurement zone separate from the measurement surface or prebound to the immobilized measurement specific binding reagent, is labelled or unlabelled, and specifically binds the ligand at an epitope different from an epitope to which the measurement specific binding reagent or said first ancillary specific binding reagent specifically binds to, and

(2) the calibration zone comprises

(c) a known amount of a releasable second ancillary specific binding reagent and a calibration surface comprising an immobilized calibration specific binding reagent having binding sites identical in structure to those of the immobilized measurement specific binding reagent and which is capable of specifically binding with at least one of (i) an unknown amount of the ligand, (ii) a known amount of the ligand and (iii) the second ancillary specific binding reagent, or

(d) a calibration surface comprising a known amount of immobilized label, wherein the second ancillary specific binding reagent is provided either on a surface of the calibration zone separate from the calibration surface or prebound to the immobilized calibration specific binding reagent, and is (i) a labelled or unlabelled specific binding partner for the ligand or (ii) a known amount of the ligand prebound to a labelled specific binding partner for said ligand, and

(3) the releasable reagents remain in their respective zones without mixing with each other in the method following either sequential or simultaneous contact with the liquid sample (a) to form a labelled measurement complex immobilized on the measurement surface in an amount dependent on the amount of the ligand present in the liquid sample and (b) to provide a calibration signal by (c) forming either a labelled calibration complex immobilized on the calibration surface in an amount either dependent on or independent of the amount of the ligand present in the liquid sample or (d) due to said known amount of immobilized label on the calibration surface; and

(B) measuring and comparing the amount of label on the measurement and calibration surfaces to determine the presence or amount of the ligand in the liquid sample.

12. A capillary-fill biosensor device suitable for use in assaying a ligand in a liquid sample, said device comprising (1) a measurement zone, (2) at least one spatially distinct calibration zone and, optionally, (3) at least one spatially distinct auxiliary calibration zone wherein

(1) the measurement zone comprises (a) a known amount of a releasable first ancillary specific binding reagent and (b) a measurement surface comprising an immobilized measurement specific binding reagent capable of specifically binding with at least one of the ligand, the first ancillary specific binding reagent, or a first binding partner which specifically binds to said ligand and said first ancillary specific binding reagent, wherein the first ancillary specific binding reagent is provided either on a surface of the measurement zone separate from the measurement surface or prebound to said immobilized measurement specific binding partner reagent,

(2) the calibration zone comprises

(c) a known amount of at least one releasable second ancillary specific binding reagent and a calibration surface comprising an immobilized calibration specific binding reagent having binding sites identical in structure to those of the immobilized measurement specific binding reagent and capable of specifically binding binding with at least one of the ligand, the second ancillary specific binding partner and a second binding partner which specifically binds to said ligand and said second ancillary specific binding reagent, and, optionally,

(3) the auxiliary calibration zone comprises

(d) an auxiliary calibration surface comprising an immobilized first auxiliary nonspecific binding reagent, wherein the releasable reagents remain in their respective zones without mixing with each other in the assay following either sequential or simultaneous contact with the liquid sample to provide (a) a specific binding complex immobilized on the measurement surface which is correlative of the presence or amount of the ligand in the liquid sample, (b) a calibration specific binding complex immobilized on the calibration surface as a result of an identical specific binding reaction as occurs on the measurement surface so as to provide a measurement correlative of a known amount of said ligand and, optionally, (c) a nonspecific binding complex immobilized on the auxiliary calibration zone to provide a measurement for correcting nonspecific background binding.

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L17: Entry 13 of 18 File: USPT Oct 12, 1993

DOCUMENT-IDENTIFIER: US 5252459 A
TITLE: Indicator reagents, diagnostic assays and test kits employing organic polymer polymer latex particles

CLAIMS:

11. The indicator reagent according to claim 1, wherein said specific binding member member of said indicator reagent is specific for a substance selected from the group group consisting of the analyte as in a sandwich assay, a capture reagent as in a competitive assay and an ancillary specific binding member as in an indirect assay.

14. A method for determining the presence or amount of an analyte in a test sample, comprising:

a. contacting the test sample sequentially or simultaneously with an indicator reagent and a capture reagent, directly or indirectly attached to a specific binding member, said indicator reagent comprising an organic polymer latex particle prepared from the polymerization of a plurality of nonchromophoric monomers, said particle having light absorbance characteristics resulting from a conjugated structure from the polymerization of said monomers wherein said polymer latex particle exhibits increased absorbance in the visible spectrum compared to the absorbance in the visible spectrum of the aggregate of nonchromophoric monomers from which it is prepared; and

b. allowing said indicator reagent to bind to the analyte in the test sample or to said capture reagent;

c. detecting said indicator reagent; and

d. determining thereby the presence or amount of analyte in the test sample.

26. The method according to claim 14, wherein said specific binding member of said indicator reagent is specific for a substance selected from the group consisting of the analyte as in a sandwich assay, a capture reagent as in a competitive assay and an ancillary specific binding member as in an indirect assay.

31. The method according to claim 29, wherein said specific binding member of said capture reagent is specific for a substance selected from the group consisting of the analyte as in a sandwich assay, said indicator reagent as in a competitive assay assay and an ancillary specific binding member as in an indirect assay.

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DOCUMENT-IDENTIFIER: US 6174665 B1
TITLE: Hormone replacement therapy monitoring

CLAIMS:

1. A method for monitoring the effectiveness of hormone replacement therapy in a perimenopausal woman, comprising

a. obtaining a body fluid sample from the perimenopausal woman;

b. testing for hormonal levels in the body fluid of the perimenopausal woman at intervals of between about 7 days to about 90 days, wherein testing for hormonal levels comprises testing for levels of at least one of progesterone, testosterone, estradiol, follicle stimulating hormone, and estriol; and

c. adjusting levels of replacement hormone administered to the woman based on the test results.

2. A method for monitoring the effectiveness of hormone replacement therapy in a early menopausal or late menopausal woman, comprising:

a. obtaining a body fluid sample from the perimenopausal woman;

b. testing for hormonal levels in the body fluid of the perimenopausal woman at intervals of between about 30 days to about 180 days, wherein testing for hormonal levels comprises testing for levels of at least one of progesterone, testosterone, estradiol, follicle stimulating hormone, and estriol; and

c. adjusting levels of replacement hormone administered to the woman based on the test results.

5. A kit for monitoring the effectiveness of hormone replacement therapy in a perimenopausal woman, comprising:

a. a fluid collection device;

b. instructions for using the fluid collection device for monitoring the effectiveness of hormone replacement therapy in a menopausal woman according to the method of claim 1.

6. A kit for monitoring the effectiveness of hormone replacement therapy in a early menopausal or late menopausal woman, comprising:

a. a fluid collection device;

b. instructions for using the fluid collection device for monitoring the effectiveness of hormone replacement therapy in a menopausal woman according to the method of claim 2.